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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,762	09/03/2002	David B Weiner	UPAP-0495	8614
34137 7590 01/04/2007 COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			EXAMINER OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/04/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/980,762

Applicant(s)

WEINER ET AL.

Examiner

ILIA OUSPENSKI

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 - 2, 10 - 13, 16 - 22, and 41 - 88 is/are pending in the application.
- 4a) Of the above claim(s) 16 - 22, 48 - 54, 61 - 67, and 75 - 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 2, 10 - 13, 41 - 47, 55 - 60, 68 - 74, and 82 - 88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/21/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. Applicant's amendments/remarks, filed 10/16/2006, are acknowledged.

Claims 82 – 88 have been added.

*Claims 1 – 2, 10 – 13, 16 – 22, and 41 – 88 are pending.*

Claims 16 – 22, 48 – 54, 61 – 67, and 75 – 81 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

***Claims 1 – 2, 10 – 13, 41 – 47, 55 – 60, 68 – 74, and 82 – 88 are under consideration in the instant application.***

2. This Office Action will be in response to applicant's amendment and arguments, filed on 10/16/2006.

The rejections of record can be found in the previous Office Action, mailed on 04/14/2006.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

It is noted that New Grounds of Rejection are set forth herein.

***3. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.***

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4. Claims 82 and 83 are objected to because of an apparent typographical error in the recitation "coding encodes," wherein "coding sequence encodes" appears to have been intended.

5. Claims 1 – 2, 10 – 13, 41 – 47, 55 – 60, and 68 – 74 stand rejected, and newly added claims 82 – 88 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 – 2, 10 – 13, 41 – 47, 55 – 60, 68 – 74, and 82 – 88 are indefinite in the recitations of "functional fragment," because it is unclear which functions are encompassed by the claim. One of ordinary skill in the art would be aware that costimulatory molecules like CD80 possess multiple functions, including, for example, affecting T cell survival, cell cycle progression, migration, and cytokine secretion. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Applicant asserts that the recitation is clear and definite in view of the specification.

In the absence of evidentiary support or reasoning, Applicants assertion is not found convincing.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims.

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6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

7. Claims 1 – 2, 10 – 13, 41 – 47, 55 – 60, 68 – 74, and 82 – 88 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment does not point out the support for the newly added limitations, and the specification as-filed or original claims do not appear to provide adequate written description of the following limitation of claim 1: CD80 protein that is free of "all or part of the CD80 region."

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

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8. Claims 1 – 2, 10 – 13, 41 – 47, 55 – 60, and 68 – 74 stand rejected, and newly added claims 82 – 88 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a nucleic acid molecule that comprises a sequence encoding a CD80 mutant protein comprising “80V that is the variable domain of CD80,” “86V that is the variable domain of CD86,” etc., does not reasonably provide enablement for a molecule comprising “80V that is the variable domain of CD80 or a functional fragment thereof,” “86V that is the variable domain of CD86 or a functional fragment thereof,” etc.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the reference of Metzler et al. does not support the position that those skilled in the art would question Applicant's assertion that the invention is enabled.

This is not found persuasive, because Metzler et al. show the unpredictability of the art of determining which amino acids in a polypeptide are essential for function. Therefore, a person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. Without detailed direction as to which sequences are essential to the function of the polypeptide, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of possible fragments encompassed by the instant claims would share the function of the respective complete polypeptides.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

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9. Claims 13, 47, 60, and 74 stand rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

The specification does not provide a sufficient enabling description of a "vaccine or attenuated vaccine" comprising a nucleic acid molecule of the invention.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the reference of Singh et al. does not support the position that those skilled in the art would question Applicant's assertion that the invention is enabled.

This is not found persuasive, because Singh et al. show the unpredictability of the art of making and using nucleic acids which possess the properties of a prophylactically or therapeutically effective adjuvant. In view of this unpredictability, and given the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided, the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

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10. Claims 1 – 2, 10 – 13, and 41 – 47 stand rejected, and newly added claims 83 – 88 are rejected under **35 U.S.C. 102(b)** as being anticipated by Linsley et al. (US Patent No. 5,580,756; 12/03/1996; see entire document), as evidenced by the instant specification at page 5, last paragraph.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant asserts that the polypeptides taught by Linsley et al. would, contrary to the requirements of the instant claims, provide the negative signal associated with wild-type human CD80 C region interactions with human CTLA4.

In the absence of evidentiary support or reasoning, Applicants assertion is not found convincing.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

**11. Conclusion: no claim is allowed.**

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

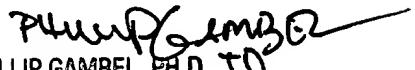
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ILIA OUSPENSKI, Ph.D.

Patent Examiner

Art Unit 1644

December 26, 2006

  
PHILLIP GAMBEL, Ph.D. JD  
PRIMARY EXAMINER  
TC 1600  
12/27/06